

FEB 12 2010

**510(k) Summary for
Dimension® EXL™ B12 and
Dimension® EXL™ FOL Methods**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K093631

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Siemens Healthcare Diagnostics Inc.
Newark, Delaware 19714-6101

Contact Information: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: A. Kathleen Ennis
Tel: 302-631-9352
Fax: 302-631-6299

Preparation date: November 17, 2009

2. Device Name:

B12 Flex® Reagent Cartridge

Classification: Class II

Product Code: CDD

Panel: Clinical Chemistry (75)

FOL Flex® Reagent Cartridge

Classification: Class II

Product Code: CGN

Panel: Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dimension Vista® B12 Flex Reagent Cartridge – K071224

Dimension Vista® Folate Flex Reagent Cartridge – K071224

CONFIDENTIAL

4. Device Descriptions:

B12

The B12 method is an *in vitro* diagnostic device that consists of pre-packaged reagents in a plastic eight well cartridge for use on the Dimension EXL™ integrated chemistry system.

The vitamin B12 method is a homogeneous, competitive chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and biotinylated intrinsic factor (IF). The first bead reagent (Chemibeads) is coated with a B12 derivative and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The patient sample is pretreated with Sodium Hydroxide (NaOH) to release the serum B12 from its carrier proteins. Potassium cyanide (KCN) is added to convert all the forms of B12 into a single, cyanocobalamin form, and dicyanocobinamide is added to keep the B12 from rebinding with the carrier proteins. After the sample pretreatment, the biotinylated IF and chemibead reagents are added sequentially to the reaction vessel. Vitamin B12 from the sample competes with the B12-chemibead for a limited amount of biotinylated IF. Sensibeads are then added and bind to the biotin to form bead pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from the Sensibeads which diffuses to the Chemibeads triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the concentration of vitamin B12 in the sample.

Folate

The FOL method is an *in vitro* diagnostic device that consists of pre-packaged reagents in a plastic eight well cartridge for use on the Dimension EXL™ integrated chemistry system.

The Folate method is a homogeneous, competitive chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and labeled folate binding protein (FBP). The first bead reagent (Chemibeads) is coated with a folic acid derivative and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. Before the immunological portion of the reaction is initiated, the patient sample is pretreated with Sodium Hydroxide (NaOH) and Dithioerythritol (DTE) to release serum folate from endogenous folate binding protein (FBP) and to maintain 5-methyltetrahydrofolate in its reduced form. After the sample pretreatment, chemibeads and labeled folate binding reagent are added sequentially to the reaction vessel. Folate from the patient sample competes with the folate-chemibead for a limited amount of labeled FBP. Sensibeads are then added and bind to the biotinylated portion of the labeled FBP to form bead pair immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from the Sensibeads which diffuses to the Chemibeads triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the concentration of folate in the sample.

5. Device Intended Uses:

The B12 method is an *in vitro* diagnostic test for the quantitative measurement of Vitamin B12 in human serum and plasma on the Dimension EXL™ integrated chemistry system.

The FOL method is an *in vitro* diagnostic test for the quantitative measurement of folate in human serum and plasma on the Dimension EXL™ integrated chemistry system.

6. Summary of the devices technological characteristics

The Dimension B12 Flex® reagent cartridge has the same technological characteristics as the Dimension Vista® B12 Flex reagent cartridge. A comparison of features is provided.

Feature	Predicate Device: Dimension Vista® B12 Flex® reagent cartridge (K071244)	New Device: Dimension® B12 Flex® reagent cartridge
Intended Use	Both test systems are for <i>in vitro</i> diagnostic use for the quantitative measurement of B12 in human serum and plasma.	
Sample Type	Both devices are for use with human serum and plasma.	
Analytical Measuring Range	The Dimension Vista® B12 method has an assay range of 50 – 2000 pg/mL	The Dimension® B12 method has an assay range of 56 – 2000 pg/mL
Technology	Both devices use LOCI® technology.	
Sample size	Uses 15 µL of serum or plasma and has a dilution ratio of 1:11 in the extracting step.	Uses 12 µL of serum or plasma and has a dilution ratio of 1:10 in the extracting step.
Reagents	Both systems use the same reagents.	
Instrument	The Dimension Vista® B12 Flex® is run on the Dimension Vista® System.	The Dimension® B12 Flex® is run on the Dimension® EXL integrated chemistry System.

The Dimension FOL Flex® reagent cartridge has the same technological characteristics as the Dimension Vista® FOL Flex reagent cartridge. A comparison of features is provided.

Feature	Predicate Device: Dimension Vista® FOL Flex® reagent cartridge (K071244)	New Device: Dimension® FOL Flex® reagent cartridge
Intended Use	Both test systems are for <i>in vitro</i> diagnostic use for the quantitative measurement of FOL in human serum and plasma.	
Sample Type	Both devices are for use with human serum and heparinized plasma.	
Analytical Measuring Range	The analytical measuring range for both methods is 0.5 – 20 ng/mL	
Technology	Both devices use LOCI® technology.	
Sample size	Both methods use 10 µL of sample.	
Reagents	Both systems use the same liquid reagents and has the same reaction concentrations for all reagents.	
	The Dimension Vista® FOL Flex® uses four (4), 70 mg tablets per well which contain a total of 26 mg of DTE.	The Dimension FOL Flex® uses one (1), 95 mg tablet per well which contains 26 mg of DTE.
Instrument	The Dimension Vista® FOL Flex® is run on the Dimension Vista® System.	The Dimension® FOL Flex® is run on the Dimension® EXL integrated chemistry System.

7. Method Comparison

A split sample method comparison was conducted using the Dimension® B12 Flex® reagent cartridge vs. the Dimension Vista® B12 Flex® reagent cartridge. Two hundred and thirty- three (233) human serum samples ranging from 68 to 1920 pg/mL were used.

The data was analyzed using least squares linear regression. The analysis is as follows:

Slope = 0.98
y-intercept = 19.0 pg/mL
 $r = 0.995$
 $n = 233$

A split sample method comparison was conducted using the Dimension® FOL Flex® reagent cartridge vs. the Dimension Vista® FOL Flex® reagent cartridge. One hundred and thirty-eight (138) human serum samples ranging from 0.6 to 19.2 ng/mL were used. The data was analyzed using least squares linear regression. The analysis is as follows:

Slope = 1.01
y-intercept = 0.05 ng/mL
 $r = 0.99$
 $n = 138$

8. Conclusion

Based on a review of the devices technological features and the method comparison study, the Dimension® B12 Flex® reagent cartridge is substantially equivalent to the legally marketed device, the Dimension Vista® B12 Flex® reagent cartridge.

Based on a review of the devices technological features and the method comparison study, the Dimension® FOL Flex® reagent cartridge is substantially equivalent to the legally marketed device, the Dimension Vista® FOL Flex® reagent cartridge.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics Inc.
c/o Anna Marie Kathleen Ennis
Regulatory Affairs Technical Specialist
500 GBC Drive,
P.O. Box 6101
Newark, DE 19714, USA

FEB 12 2010

Re: k093631
Trade/Device Name: Dimension® B12 Flex® Reagent Cartridge and Dimension® FOL Flex®
Reagent Cartridge
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B12 Test System
Regulatory Class: Class II
Product Code: CDD and CGN
Dated: January 15, 2009
Received: January 19, 2009

Dear Ms. Ennis

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k093631

Device Name: Dimension® B12 Flex® reagent cartridge

Indications for Use:

The B12 Flex® reagent cartridge is an in vitro product for the quantitative measurement of Vitamin B12 in human serum and plasma on the Dimension® EXL™ integrated chemistry system. Measurements of vitamin B12 are used in the diagnosis and treatment of anemias of the gastrointestinal malabsorption.

Prescription Use xx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k09 3631

Indications for Use Form

510(k) Number (if known): k093631

Device Name: Dimension® FOL Flex® reagent cartridge

Indications for Use:

The FOL Flex® reagent cartridge is an in vitro product for the quantitative measurement of Folate in human serum on the Dimension® EXL™ integrated chemistry system. Measurements of folate are used in the diagnosis and treatment of megaloblastic anemia

Prescription Use xxxx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k093631